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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,677	03/25/2004	Francis C. Wessling, JR.	322101.1030	6200

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EXAMINER	
MCCRAW, BARRY CLAYTON	
ART UNIT	**PAPER NUMBER**
3744	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,677	WESSLING, ET AL.	
	Examiner	Art Unit	
	B. Clayton McCraw	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13,15-17 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-17* is/are allowed.

6)☒ Claim(s) *1-8,10-13 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/25/2006 have been fully considered but they are not persuasive. The applicant argues that the Johnson reference fails to teach a mixture of water and deuterium oxide that provides a desired phase change temperature in a range above zero degrees Celsius and below 3.8 degrees Celsius. The examiner respectfully disagrees. Column 2, lines 57-68 clearly illustrate the fact that deuterium oxide has a normal freezing point of around 4 degrees Celsius and various amounts of water can be added to create a freezing point anywhere from there, all the way down to negative 4 degrees Celsius. As shown by the statements "the freeze point of the mixture may be raised accordingly to accommodate particular needs" and "in order to fine tune the device so that an indication is given for a predetermined temperature, an amount of deuterium oxide may be added to the water," it is clear that the subrange that the applicant provides which is within the range that Johnson explains would be obvious to one of ordinary skill in the art by routine experimentation. Additionally, the applicant claims that Johnson does not disclose the phase change material positioned in close proximity to a biological material. The examiner submits that independent claim 1 is directed to a phase change material, specifically, and the phrase "positioned in close proximity to a biological material such that a temperature of the biological material is maintained near the desired phase change temperature" is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight. Additionally, for further support of this statement, Douglas Hamilton

(US 4,530,816) explicitly teaches utilizing a cooling device for cooling a biological material (col. 2, lines 26-31).

Regarding the applicant's argument that Johnson and Hjertstrand et al. are not analogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In this case, the Johnson and Hjertstrand references meet both criteria. Both references teach toward providing or utilizing a phase change material in an effort to provide this material to cool to near or around zero degrees Celsius. The applicant also argues that neither Hjertstrand or Johnson have any apparent disadvantages that would require modification. This however, has no bearing on whether modification could or would be advantageous for any particular endeavor outside of the invention's original use.

Regarding the applicant's argument that there lacks a reason to combine Hjertstrand et al. and Johnson, it should be noted that both references teach toward providing or utilizing a phase change material in an effort to provide this material to cool to near or around zero degrees Celsius. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the container of Hjertstrand et al. with the phase change material of Johnson because deuterium oxide enables the container to maintain the specific temperature range of approximately 0-5 degrees Celsius, with the proper mixture determined through experimentation (col. 2, lines 57-65).

This Office Action is being made final. The examiner's rejection appears below, in response to the applicant's claim amendments.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 10-12, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 4,191,125). Johnson explicitly teaches the method and apparatus of a phase change material having a selectable phase change temperature in a range between approximately zero degrees Celsius and 3.8 degrees Celsius (col. 2, lines 57-69) comprising a mixture of water and deuterium oxide (col. 2, line 59) wherein a mole fraction of deuterium oxide is selected to provide a desired phase change temperature (col. 2, lines 57-60), a nucleating agent being added to the mixture (col. 2, lines 38-44), adding a colorant to the mixture (col. 3, lines 12-23), and storing a temperature sensitive material in an environment requiring temperatures between approximately zero degrees Celsius and 3.8 degrees Celsius (col. 1, lines 5-10 and col. 3, lines 6-23), a pack for holding the phase change material (col. 2, lines 33-37) wherein the pack is shaped to conform for a desired treatment (Figure 1, item 3; "ampule" shaped as a freeze indicator), the sensitive material thermally isolated from the environment (col. 1, lines 6-19), and wherein the sensitive material is a biomaterial (col. 2, lines 46-63).

Regarding claim 1, the phrase, "positioned in close proximity to a biological material such that a temperature of the biological material is maintained near the desired phase change temperature," is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight.

Regarding claim 10, the phrase, "for use in physical therapy in order to maintain live tissue within a desired temperature range," is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight.

Regarding claim 21, the phrase, "positioning the phase change material close to a biological material such that a temperature of the biological material is controlled by the phase change material," is the material's intended use, and is not a functional limitation of the material itself, and therefore holds limited patentable weight.

Regarding claims 22-27, the biological materials disclosed constitute the material's intended use, and not a functional limitation of the material itself, and therefore holds limited patentable weight.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125) in view of Douglas-Hamilton (US 4,530,816). Johnson teaches the elements of the invention as described above, but fails to teach a gel material added to the mixture. Douglas-Hamilton explicitly teaches a gel material added to the mixture (col. 2, lines 66-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phase change material of Johnson with the gel material of Douglas-Hamilton because adding gel to a thermal mixture increases the thermal capacity of the mixture.

7. Claim 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hjertstrand et al. (US 4,145,895) in view of Johnson (US 4,191,125) Hjertstrand et al. explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1), but fail to teach the mixture of water and deuterium oxide as described above. Johnson

explicitly teaches the mixture of water and deuterium oxide as described above, but does not teach a temperature depression material, placing the phase change material in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material, or providing a container for holding the sensitive material. placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the container of Hjertstrand et al. with the phase change material of Johnson because deuterium oxide enables the container to maintain the specific temperature range of approximately 0-5 degrees Celsius, with the proper mixture determined through experimentation (col. 2, lines 57-65).

Allowable Subject Matter

8. Claims 15-17 are allowable.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Clayton McCraw whose telephone number is (571) 272-3665. The examiner can normally be reached on M-F 8:30AM-5:00PM.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571) 272-4834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BCM
11/16/2006

CHERYL TYLER
SUPERVISORY PATENT EXAMINER